

Joint Commission on Health Care

Opt-Out Program for Organ, Eye, and Tissue Donation (HJR 19 – Delegate O'Bannon)

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Organ, Eye and Tissue Donation

- ▶ Process of recovering organs, eyes, and tissues from a deceased person and transplanting them into others in order to save the lives or improve the health of those in need.
 - Up to nine lives can be saved through organ donation.
 - Another 50 lives or more may be improved through tissue donation.

House Joint Resolution 19 (HJR 19)

- ▶ Directs the Joint Commission on Health Care (JCHC) to study options for establishing an opt-out program for organ, eye and tissue donation in the Commonwealth.

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The Need to Increase the Availability of Organs for Donation

- ▶ According to Donate Life America:
 - As of July 2012, there were 114,712 patients waiting for an organ donation.
 - Every 10 minutes another name is added to the national organ transplant waiting list.
 - Approximately 6,000 people die waiting for a transplant each year.
 - While 90% of Americans say they support donation, only 30% know the essential steps to become a donor.

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Opt-in Organ Donation Process

- ▶ Virginia, as does the entire U.S., operates by an opt-in organ donation process.
- ▶ Rooted in a recognition of individual rights and voluntarism and governed by the Uniform Anatomical Gift Act (UAGA). It provides:
 - Any person older than 18 can make a gift, effective upon death, of all and any part of his/her body.
 - When the deceased has not expressly made a gift or expressly objected to donation during his/her lifetime, the deceased's family can make a gift. Expressly allows gifts to be made by will, effective immediately upon death, or by donor card, and can be revoked at any time.
 - Shields all persons acting in good faith from civil and criminal liability

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To Be an Organ, Eye or Tissue Donor In Virginia

- ▶ A person can either:
 - Say “yes” to donation at the Department of Motor Vehicles (DMV).
 - Any person who has indicated “yes” at the DMV is included on the DonateLifeVirginia.org, online registry.
 - You must check “yes” to donation every time you renew your driver’s license or state identification card to remain on the donor registry.
 - Directly register to be an organ, eye or tissue donor on the Virginia Registry, DonateLifeVirginia.org.

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Familial Role in Donation Process

- ▶ *Virginia Code* §54.1-2986 states:
 - “Regardless of the absence of an advance directive, if the patient has expressed his intent to be an organ donor in any written document, no person noted in this section shall revoke, or in any way hinder, such organ donation.”
 - Family members “noted” in *Code* §54.1-2986; patient’s guardian, spouse, adult child, parent, adult sibling, and “other relative...in descending order of blood relationship...”
- ▶ In addition, in the absence of an individual’s expressed desire to be an organ donor, a family member may give permission to have the individual’s organs donated.

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Organ Procurement and Transplantation Network (OPTN)

- ▶ The National Organ Transplant Act (NOTA) of 1984 established the Organ Procurement and Transplantation Network (OPTN), a unified transplant network of 58 federally- designated Organ Procurement Organizations (OPOs).
 - By federal law, OPOs are the only organizations that can perform the life-saving mission of recovering organs from deceased donors for transplantation.
 - OPOs are regulated by multiple government agencies and required to adhere to the highest medical and ethical standards.
- ▶ The OPTN is a unique public-private partnership that links all of the professionals involved in the donation and transplantation system.
- ▶ The United Network for Organ Sharing (UNOS) administers the OPTN under contract with the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services.

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The Process in Practice

- ▶ A person who may benefit from a transplant is referred by his/her doctor to a transplant center, which evaluates the patient.
- ▶ The transplant center runs a number of tests and considers the patient's mental and physical health, as well as his/her social support system.
- ▶ If the center decides to accept this person as a transplant candidate, they will add his/her medical profile to the national patient waiting list for organ transplant.
- ▶ The candidate is not placed on a ranked list at that time. Rather, his or her information is kept by UNOS in a constantly updated, computerized database.
- ▶ When a deceased organ donor is identified, a transplant coordinator from an organ procurement organization accesses the UNOS computer.
- ▶ Each patient in the database is matched by the computer against the donor characteristics.
- ▶ The computer then generates a ranked list of candidates for each available organ in ranked order according to the organ allocation policies of the organ procurement and transplantation network.

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The Process in Practice

- ▶ The organ allocation and distribution system is designed to be blind to wealth or social status.
- ▶ National policies govern the sharing of organs in the United States to ensure all patients fair and equal access to transplantation.
- ▶ The length of time it takes to receive a transplant is based on factors including: location, severity of illness, blood type, weight, genetic typing, size, and length of time on the waiting list.

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The Process in Practice

- ▶ Organ donation is only accepted following the declaration of death by a doctor who is not involved in transplantation.
- ▶ In order to donate organs, a patient must be declared brain dead, or in cases where a family requests withdrawal of ventilator support, declared dead by cardiac criteria.
 - Brain death is the complete and irreversible loss of all brain function, including the brain stem and therefore, the patient has NO CHANCE OF RECOVERY.
 - To be a legal determination, *Virginia Code* requires two physicians to make this declaration based on clinical exams and nationally-accepted brain death testing methods.
 - It is only after all of these efforts have been exhausted and death has been declared that organ, eye and tissue donation will be considered.
 - If a match cannot be found for the organs, the organs will not be removed from the body.

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The Process in Practice

- ▶ By law, the doctors who work to save the patient's life will not be the same professionals involved in organ retrieval and transplantation.
- ▶ A patient, who is sick or injured and admitted to the hospital, will receive the same level of care regardless of whether he/she has indicated a wish to be an organ, eye and/or tissue donor.
- ▶ Doctors and hospital staff DO NOT HAVE ACCESS to the Donor Registry.
 - Only donor program personnel can access the Donor Registry – not the medical professionals taking care of the patient.

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Presumed Consent

- ▶ Because the need for organ, eye and tissue donations surpasses the supply, some argue the need for a system based on presumed consent.
- ▶ Under this system, a person is presumed to have consented to organ, eye and tissue recovery if he/she has not registered a refusal.
- ▶ Advocates indicate such a system would:
 - Improve efficiency
 - Increase supply
 - Reflect the opinion of the vast majority who favors organ donation
 - Maintain individual autonomy in the ability to opt-out, while focusing more on the needs of those on the donation waiting list.

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Systems Based on Presumed Consent

- ▶ A number of European countries have implemented a presumed consent system.
 - Austria, Belgium, Denmark, France, and the Netherlands.
 - Spain is often cited as a presumed consent country, but in fact operates a voluntary consent system.
- ▶ After these countries implemented a presumed consent system, the supply of organs did increase; however, research is unclear as to whether other factors played a bigger role than the policy of presumed consent.
 - For example, in many countries these laws are rarely enforced and family consent is always or often required before organs are extracted.
 - According to UNOS, mechanisms to protect the rights of objectors and to respect individual autonomy are lacking in those countries.

Source: Association of Organ Procurement Organizations, "Presumed Consent Resource Document." (January 2012); A Report of the Presumed Consent Subcommittee, OPTN/UNOS Ethics Committee "An Evaluation of the Ethics of Presumed Consent And A Proposal Based on Required Response" (1993).

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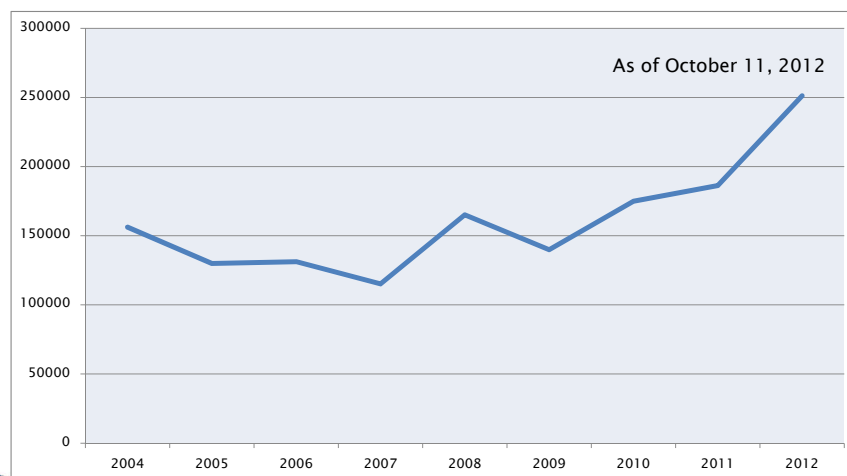
Comparison of Donation Systems

- ▶ A recent study conducted by the Association of Organ Procurement Organizations indicates that the United States already has higher donation rates than any of the countries with presumed consent systems. The Top 11 Countries:

Country	Consent Practice	Donors Per Million Population
Spain	Voluntary Consent	34.4
United States	Voluntary Consent	25.4
Belgium	Presumed Consent	25.3
France	Presumed Consent	24.7
Austria	Presumed Consent	23.0
Italy	Voluntary Consent	21.3
United Kingdom	Voluntary Consent	15.5
Germany	Voluntary Consent	14.9
Denmark	Presumed Consent	13.9
Sweden	Voluntary Consent	13.8
Netherlands	Presumed Consent	12.8

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Virginia Organ, Eye and Tissue Registrations, By Year



*Data subject to change upon Validation

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Presumed Consent in the U.S.

- ▶ If Virginia were to switch to a presumed consent system, we would be the first state in the country to do so.
- ▶ Other states, including Colorado, Delaware, Illinois, Pennsylvania, and New York have introduced legislation in the past but it has not been enacted.
- ▶ Opt-in donation efforts have been opposed by Donate Life California and other organizations whose goal is to increase organ donation and recovery rates.

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Opposition to Presumed Consent

- ▶ Opposition to presumed consent in the U.S. has been based on the opinion that the current system seems to be working well.
 - ▶ Public opinion favors organ donation and registrations continue to increase.
- ▶ However, because the majority of citizens favors individual autonomy there is a fear that moving to a presumed consent system would result in a decrease in organ donations.
 - ▶ Individuals would act out of fear or protest and decide not to donate.
 - ▶ The political environment and the majority public opinion does not favor a change.
 - ▶ Faith in the current system could be undermined negating the progress made over the last couple of decades.
- ▶ There is no hard data to indicate that moving to an opt-out donation program would increase donation and recovery rates.

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Current Efforts to Increase Donations

- ▶ In 2010, HRSA commissioned the Center for Transplant System Excellence to conduct the *Deceased Donor Potential Study* in order to develop a model for estimating donor potential over the next 5-10 years.
 - Develop evidenced-based national goals for deceased organ donation and identify strategies to best meet the projected need.
 - Believed to be necessary to improve organ procurement and measure performance of the national organ transplantation system.

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Policy Options

- ▶ **Option 1:** Provide a written report to the House Committee on Health, Welfare and Institutions without taking further action.
- ▶ **Option 2:** Provide a written report to the House Committee on Health, Welfare and Institutions with a letter from the JCHC Chair indicating that the Joint Commission voted in support of pursuing an opt-out organ donation program in Virginia.
- ▶ **Option 3:** Provide a written report to the House Committee on Health, Welfare and Institutions with a letter from the JCHC Chair indicating that the Joint Commission voted in opposition to pursuing an opt-out organ donation program in Virginia.

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Public Comment

- ▶ Written public comments on the proposed options may be submitted to JCHC by close of business on October 26, 2012.
- ▶ Comments may be submitted via:
 - E-mail: jhoyle@jchc.virginia.gov
 - Fax: 804-786-5538
 - Mail: Joint Commission on Health Care
P.O. Box 1322
Richmond, Virginia 23218
- ▶ Comments will be summarized and included in the Decision Matrix which will be discussed during the November 7th meeting.

▶ Website – <http://jchc.virginia.gov>

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